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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,436	06/30/2003	Istvan Toth	36677.11	9341

27683 7590 12/27/2006  
HAYNES AND BOONE, LLP  
901 MAIN STREET, SUITE 3100  
DALLAS, TX 75202

EXAMINER
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KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,436	<b>Applicant(s)</b> TOTH ET AL.	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-13, 16, 17, 19 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-13, 16-17, 19 and 24-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A Request for Continued Examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 10/12/2006 has been entered.

The following information provided in the Request for Continued Examination affects the instant application:

1. Claims 2 and 14-15 have been canceled.
2. New Claims 29-37 have been added.
3. Claims 3-13, 16-17 and 24-28 have been amended.
4. Remarks drawn to claim objections and rejections under 35 USC 112, first paragraph advanced in the previous office action and a Declaration of William Roy Jackson under 37 CFR 1.132.

Claims 1, 3-13, 16-17, 19 and 24-37 are pending in the case. Claims 18 and 20-23 have been withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-13, 16-17, 19 and 24-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dekany et al (Peptides, 1996, 331-32).

Dekany et al disclose a lipidic moiety containing sugar compound (page 332, structural formula 2). In this structure the lipidic moiety (shown to the right in the structure; L in instant claim 1) is attached to a monosaccharide (S in the instant claims) via a linker (NH group). The sugar bearing the lipidic moiety is attached to another sugar. A sugar molecule is a therapeutically useful molecule. Structure 2 of Dekany meets the limitations of instant formula I for W being absent.

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The linker, NH in structure 2 of Dekany, is attached to the sugar unit through the glycosidic position. The term glycosidic position is not defined by the claim. Hence any position on the sugar moiety is interpreted as a glycosidic position. Since the attachment of the lipidic moiety to the sugar is via a nitrogen atom and a CONH group is present, the attachment to the monosaccharide is via an N-glycoside and an amide bond. The linker, NH, is attached to the lipidic moiety  $C(O)CH-(NHR^2)-(CH)_2-CH_3$  group in structure 2 of Dekany, via an amide bond. In structure 2 of Dekany lipidic moiety L is composed of the group  $-C(O)CH-(NHR^2)-(CH)_2-CH_3$ . This structure is same as structure IIa for  $R_1$ = hydrogen and  $R_2$  = linear alkyl chain having 16 carbons and both  $R_1$  and  $R_2$  are not hydrogens at the same time. The lipid moiety in structure 2 of Dekany has an  $NHR^2$  group attached to it, which can be charged. In structure 2 of Dekany the sugar unit in the middle (mono saccharide) is attached to a lipidic moiety containing one lipoaminoacid meeting the structural formula IIa in instant claim 12. Dekany suggests the coupling of the conjugate of his invention to peptides and drugs (page 332, paragraph below structure 2). The physico chemical properties of the conjugates were modified by varying the nature and the number of sugars, the number of lipoaminoacids or the length of their alkyl chain. According to Dekany complexation of the conjugate (structure 2, page 332) to drugs and peptides will enhance the water solubility in drug delivery and increase the immunogenicity of synthetic peptides.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make complexes of formula I and their compositions as instantly claimed with a reasonable expectation of success since the prior art teaches the preparation of such complexes using the components as instantly claimed.

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One of ordinary skill in the art would be motivated to make such compounds and compositions since such a complex with drugs and peptides increases their water solubility and hence would be useful in drug delivery as taught by Dekany. It is well within the purview of one of ordinary skill in the art to extend this to several drugs for the purpose of enhanced drug delivery.

***Response to Applicants Remarks***

Applicants' arguments along with the supporting Declaration of William Roy Jackson have been considered and have been found to be persuasive. The rejection under 35 USC 112, first paragraph advanced in the previous office action has been dropped.

***Conclusion***

Claims 1, 3-13, 16-17, 19 and 24-37 are rejected

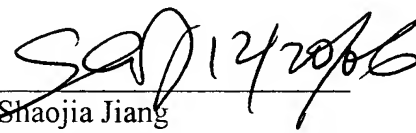
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

  
Shaojia Jiang  
Supervisory Patent Examiner  
Art Unit 1623